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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,947	12/12/2005	James N. Pettite	297/204 PCT/US	1436
25297 7590 09/06/2007 JENKINS, WILSON, TAYLOR & HUNT, P. A. SUITE 1200, UNIVERSITY TOWER 3100 TOWER BOULEVARD DURHAM, NC 27707			EXAMINER WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	
			MAIL DATE	DELIVERY MODE
			09/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/541,947		PETITTE ET AL.	
	Examiner		Art Unit	
	Michael C. Wilson		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 12-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12-19-05,6-5-06,8-15-06 & 3-14-07.

DETAILED ACTION

Claims 1-57 remain pending.

Election/Restrictions

Applicant's election of Group II, claims 1-12, and the species of DAZL in the reply filed on 6-18-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further inspection, claims 6 and 12 are drawn to the method of Group I (increasing PGC numbers). Therefore, claims 6 and 12 as well as claims 13-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6-18-07.

This application contains claims 6 and 12-57 drawn to an invention nonelected without traverse in the reply filed on 6-18-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-5 and 7-11 are under consideration as they relate to decreasing PGC numbers/development using DAZL proteins.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The amendments to the specification have been entered. The sequence listing has been entered and is correct.

DAZL-N is 17 amino acids and cannot be amino acids 2-17 of GenBank
Accession No: AAO26019 as stated on pg 51 in Table 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a method for modulating primordial germ cells (PGC) numbers in an avian embryo, the method comprising immunizing a female bird with an antigen associated with primordial germ cells, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies specific for the antigen to modulate numbers of endogenous PGCs in an avian embryo present within in the egg. Claim 1 is drawn to a method for modulating primordial germ cells (PGC) development in an avian embryo, the method comprising immunizing a female bird with an antigen associated with primordial germ cells, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies specific for the antigen to

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modulate development of endogenous PGCs in an avian embryo present within in the egg. The claims are being examined as it relates to decreasing PGC numbers/development using DAZL proteins. The only purpose for the method claimed is to repopulate the treated embryo with donor PGCs from a different strain or species of avian to make a chimeric avian. The specification does not provide a use for the method claimed without making a chimeric avian.

The specification teaches decreasing PGC numbers in an embryo using DAZL-C and DAZL-N proteins administered to female chickens (pg 55, lines 19-26; pg 56, lines 12-17). The specification suggests repopulating germ cells in treated embryos by injecting PGCs into the blood of stage 14-17 treated embryos (pg 57, lines 7-14). The specification suggests assessing the number of donor PGCs that repopulate the gonad of the recipient embryos (pg 57, lines 16-28).

The art is silent regarding treating an avian embryo to decrease PGC numbers/development and repopulating the treated embryo with donor PGCs from a different strain or species of avian to make a chimeric avian.

The absence of how to repopulate PGCs in an embryo in the art and the lack of correlative evidence in the specification fails to enable the method claimed. The specification fails to overcome the absence in the art by reasonably teaching injecting donor PGCs into a treated embryo will repopulate the treated embryo to produce a viable chimeric avian. Merely injecting donor PGCs (pg 57, lines 10-14) and assessing PGC repopulation as suggested (pg 57, lines 16-28) is inadequate to indicate PGCs would successfully repopulate the embryo or that a viable avian would be obtained. It is

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not readily apparent from the specification that donor PGCs will target the proper position in the embryo to successfully replace the PGCs destroyed by the treatment so that a viable chimeric avian will be obtained. If the method described does not produce viable chimeras, it would require those of skill undue experimentation to determine how to fix the problem because the specification provides no additional suggestions. Accordingly, the claims are not enabled for its sole intended use; decreasing PGC numbers in an avian embryo for the purpose of repopulating the embryo with donor PGCs and obtaining a viable chimeric avian.

Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of what applicants consider “sufficiently high concentration of antibodies specific for the antigen to modulate the numbers [or development] of endogenous PGCs in an avian embryo” (claims 1 and 7) are unclear. The concentration of antibodies required to decrease the number or development of PGCs is not set forth in the specification or the art at the time of filing. Accordingly, those of skill would not be able to determine when the concentration of antibodies obtained was infringing on the claim.

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The metes and bounds of what applicants consider antibodies "specific for the antigen" (claims 1 and 7) are unclear. It cannot be determine how specific the antibodies must be. Accordingly, those of skill would not be able to determine whether antibodies that recognized any DAZL antigen, for example, was encompassed by the claim of if the phrase was limited to antibodies that are specific to a particular DAZL antigen, i.e. DAZL-C or DAZL-N.

The art did not reasonable teach or suggest modulating primordial germ cells (PGC) numbers/development in an avian embryo by immunizing a female bird with an antigen associated with primordial germ cells, whereby an egg produced by the female bird comprises a sufficiently high concentration of antibodies specific for the antigen to modulate numbers/development of endogenous PGCs in an avian embryo present within in the egg.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. NCBI Sequence Listing for AAO26019, Jan 5, 2003.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke at the end.

**MICHAEL WILSON
PRIMARY EXAMINER**